



Your TEAM-PRRC association

Newsletter N°4

September 26th, 2020

Editorial

Dear members, bonjour!

Here is YOUR Newsletter. As you have noticed, we changed to a quarterly publication to improve the selection of our communication. Where, somewhere, our association has matured we aim to provide you with more attractive topics and larger in-depth discussions. You may have experienced in different subjects including MDR that any single sentence or even word could lead to strenuous discussions and even disputes on the application or interpretation of such & such an article. We want to be part of that when talking of PRRC's duties and rights!

Economic activities have a hard time to recover while time is still ticking driving us to that fateful date of this so dreaded date of MDR application. Even our authorities and notified bodies are buried under the weight of its application – with the same doubts and fears as us. The only way is to exchange, argue and discuss again and again to reach the final intent and goal: harmonisation and consensus on organisation's systems and their regulation to the benefit of all of us. Here is our raison d'être in that long chain of responsibilities and commitments.

PRRCs are responsible for compliance of devices delivering priority services to the Human community and providing patients with better lives, if not simply survival!

This association remains YOUR association so feel free to pass on this newsletter to your colleagues and acquaintances in Europe. They are all welcome.

Stay safe and keep on with compliance! With our kind regards.



The TEAM

In this issue:

Editorial	1
Your association:	2
Just for you!	2
Events:	3
To come:	4
News:	4

Your association:

Our membership continued to grow steadily during the summer. However, we still need to enhance our visibility as well as our influence to become a major stakeholder with the authorities. To that aim, we do need all of you to recruit and spread the word.

We continue to build and enlarge our network, thanks to the support from people involved in the MDR and we enjoy welcoming even more “influencers”.

We have also initiated a relationship directly with the EU MDCG and we try hard to contribute to their next revision of the guidance concerning PRRCs. For that point, we will initiate in the next days a large survey to all our active members to collect your questions, your opinion, and your interpretation of PRRC’s rights and duties. So, we will need YOU to feed that discussion and we will do our best to have some actions translated into the new guidance.

We will also present our points of view in the form of a Position Paper of TEAM-PRRC association.

The long-awaited “FORUM” is now operational in our website. Get the opportunity to exchange with other members. So [CHAT!](#)

Some of you entered the association website but have still not finalized their membership! Please join!

If you are experiencing difficulties, do not hesitate to contact us: inform@team-prrc.eu

Just for you (our active members)!

There is a new tab ([For U](#)) in our Website including opportunities and discount from our cherished sponsors for our active members. In there you can get attractive prices on training, news and regulation watches, documents and templates for your everyday activities... and much more!!



Audit and Risk Solutions, insurance broker, has agreed to propose Civil Responsibility Insurance contracts dedicated to PRRCs duties with special price to our members. A specific version for those PRRCs practicing within companies will be proposed. More details in your member space ([For U](#)). (Limited to PRRCs registered in France at this time).



From **White-Tillet**:

Special discount for all the webinars to any French TEAM-PRRC member (up to date with his membership fee). <https://white-tillet.com/>

On registration form indicate that you are member of TEAM-PRRC.



From **MDlaw.eu**:

[MDlaw annual membership](#): 43 EUR – 125 EUR – 330 EUR

TEAM-PRRC member promotion: 50% on all membership levels, starting at 23 EUR per month! The discount coupon to be shared in membership area to benefit from this 50% promotion

[>> MORE INFORMATION <<](#)



From **Obelis**:

Special discount for all PRRC members for the upcoming EAAR Annual Conference on New Medical Device Regulations:

[>> MORE INFORMATION <<](#)



From **DM Experts**:

On line MDR (EU) 2017/745 training course (French only); 6 months continuous access and including 2-hour-live session of Questions and Answers:

Individual Rate : 750€ >> TEAM-PRRC members special rate : 500€

<https://academie.dm-experts.fr/formations/formation-en-ligne-au-reglement-ue-2017-745/>

Special 20% discount on one year “Premium” subscription to “Flash de DM Experts” articles

Online training about artificial intelligence for Medical Devices : 20% discount.

More information on: <https://academie.dm-experts.fr/produit/intelligence-artificielle-et-dm/>

Request your promo code here to inform@team-prrc.eu

Events



TEAM-PRRC Webinars

TEAM-PRRC successfully lead two “inaugural” webinars about the most important things to know regarding the Persons Responsible for Regulatory Compliance according to the article 15 of MDR & IVDR. Two sessions were recorded and available at [WEBINARS++](#) in our website.



MedtecLIVE

TEAM-PRRC association was registered at [MedTecLIVE](#) Summit Congress which was held virtually from 30 June to 2nd July 2020.

It was the first event fair that TEAM-PRRC attended. We met key regulatory affairs speakers and consultant and other well-known companies.



Easy Medical Device Podcast

TEAM-PRRC was invited to Easy Medical Device Podcast organized by Monir El Azzouzi. Elem Ayne and Anne Jury, our presidents were interviewed about the role of the PRRCs and their liabilities. The video of that podcast is available at [WEBINARS++](#) in our website.

We thank Monir El Azzouzi for his warm invitation to his podcast. It was a useful podcast that allow TEAM-PRRC to win the consideration of more persons who met the qualifications of the PRRC and who became a member of our association

Monir's podcasts are short and sweet! Elem and I enjoyed very much doing this interview with Monir as he makes the rather dry subject of regulations easy to digest. It was the first time I had ever done a podcast and Monir put us at our ease very quickly whilst still getting to the heart of the topic of PRRC. I hope we will do more and Elem has already worked with Monir on his Green Belt Certification. [Have a look for yourself.](#)



MED'INOV 2020 TEAM-PRRC was there !!

TEAM-PRRC participated this event on 9 & 10 September 2020 in Lyon (Fr) together with our partner and sponsor DM Experts. It was a big pleasure to meet physically some manufacturers, subcontractors, CRO, well-known consulting and certification firms, validation laboratories and a notified body. We wish to find a way of collaboration with these organizations and reach more and more PRRCs.



TEAM-PRRC Q/A webinar october 2020

Preparing the questions for this particular session:

TEAM-PRRC is preparing a new session of webinars in the form of Q&A and it will be open to all people interested to attend. You can ask your questions as from now by sending them to our email address inform@team-prrc.eu (please insert TEAM-PRRC Q/A webinar October 2020 in title) or sharing them in the forum (for our members).

Thanks to that session, all people could know more about what TEAM-PRRC activities and its objectives. We hope that this will be useful and fruitful to all of you. We aim to gather for this event a list of questions clearly formulated to be forwarded to the EU commission and the MDCG. This will help to establish our presence as a major stakeholder when talking about PRRCs.

To come



TEAM-PRRC @ La rentrée du DM

TEAM-PRRC will be present in its first face to face event at the “8ème Édition de la rentrée du DM” on 29-30 September 2020 in Besançon (France).

Join and meet us in our booth 23 during this major event dedicated to Medical Devices.



TEAM-PRRC @ La Journée du DM

TEAM-PRRC will be present at face to face event at the “6ème Rencontres Internationales des DM” on 5th November 2020 in Nimes (France).

Our sponsors: visit them on our [website](#)!



News

We talk about us!

To promote your TEAM-PRRC Association, we now have our striking motto “**Compliant together**” as the fruit of our doodle poll. Here is our first banner!!

That’s all for this issue of YOUR association newsletter.

Hope you enjoyed.

Hear from you very soon.

The TEAM

